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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/643,579	08/22/2000	Richard Martin Broglie	BB1334 USNA CNT1	3114
26191	7590	02/17/2004	EXAMINER	
FISH & RICHARDSON P.C. 3300 DAIN RAUSCHER PLAZA 60 SOUTH SIXTH STREET MINNEAPOLIS, MN 55402			KALLIS, RUSSELL	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/643,579	BROGLIE ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23,25,29 and 37-59 is/are pending in the application.
- 4a) Of the above claim(s) 45-48 and 59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23,25,29,37-44 and 49-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/22/2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/20/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 23, 25, 29, and 37-59 are pending. Claims 59 and 45-48 are withdrawn. Claims 23, 25, 29, 37-44 and 49- 58 are examined.

The rejection of Claims 1-9, 24, 29 and 36 under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicant's amendments.

Double Patenting

Rejection of Claims 1-9, 23-25, 29, and 36 under the judicially created doctrine of obviousness-type double patenting is withdrawn in view of Applicant's amendments and arguments.

Rejection of Claims 1-9 and 36, provisionally rejected under the judicially created doctrine of obviousness-type double patenting is withdrawn in view of Applicant's amendments.

Claim Rejections - 35 USC § 102

Rejection of Claims 1-9, 23-25, 29, and 36 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,372,965 is withdrawn in view of Applicant's amendments and arguments.

Drawings

The drawings are objected to because the figure labels are illegible and should be replaced with computer generated text. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Election/Restrictions

Newly submitted Claims 59 and 45-48 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The method of making a vegetable oil that comprises oil from the seeds of a plant has different method steps than the methods of making alterations to the fatty acid composition of plant seeds. Thus the method of making a vegetable oil is a separate and distinct invention. The method of Claims 45-48 is drawn to a method of altering fatty acid composition in a plant seed comprising transformation of a plant using a delta 15 fatty acid desaturase that differs from the method of Group I that uses a delta 12 fatty acid desaturase. Thus, the methods of Group I and II of altering a fatty acid composition in plant seeds are drawn to different polynucleotides that encode distinct enzymes that have discrete catalytic activities producing different products in varying degrees. Thus the inventions of Group and Group II are distinct.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 59 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

Claim 38 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In Claim 38, the recited Ala-His-Lys-Cys-Gly-His does not

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indicate that there is a mutation and merely substitutes one conserved amino acid sequence for another and The Lys is not in Claim 23. Further, "mutant" is misspelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23, 25, 29 remain and new Claims 37-44 and 49-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant asserts that cancellation of Claims 1-9 and 36 in combination with the amendment of Claim 23 have overcome the written description rejection because Applicant has disclosed a mutant to the claimed conserved region in Examples 1-4 of the specification (response page 8).

The claims are drawn to a mutant microsomal delta 12 having mutations in conserved amino acid positions 104-109 (see Table 1, page 17 of the specification i.e. referenced as region 3 in the Table). Applicant recites the consensus sequence for either a mutant microsomal or plastidial delta 15 enzyme and a microsomal delta 12 enzyme. Clearly the claim does not provide a clear written description of a conserved region for a delta 12 enzyme or the mutation to said region that embodies the invention. Further, Example 1, page 28 describes mutations, E to K in lines 11-12 and an L to H mutation that does not fall within the region of Claim 23 in line 33.

Thus, Applicant's remarks that the specification describes a mutation in the recited region that rendered the delta-12 fatty acid desaturase non-functional is only supported by the mutation taught by the D gene (i.e. SEQ ID NO: 3) amino acid residues 104-109 (A-H-K-C-G-H).

Furthermore the disclosure of a single sequence (i.e. a single amino acid residue charge at a particular location) does not adequately describe a genus, per University of California (*See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997)). In addition, Claims 23, 29, 37, and 38 are broadly drawn to any mutation at the prescribed amino acid positions that eliminate delta-12 desaturase activity and since Applicant teaches only one example of the claimed genus, the requirements of University of California are not met.

Claims 23, 25, 29 remain and new Claims 37-44 and 49-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant asserts that the examples of the specification is enabling for the claimed invention and that it is within the purview of one of skill in the art to determine the effect upon desaturase activity of mutations within the claimed conserved sequence of the delta-12 fatty acid desaturase (response page 9).

The examples of the specification do not teach how to make any mutations that would result in the desired product. Applicant only teaches recovery of a natural mutation taught in SEQ ID NO: 3, within the region of the delta 12 enzyme as claimed in Claim 23, that resulted in an altered fatty acid composition similar to that in the when transformed into a plant. Further, the

specification does not provide guidance for making the predictable changes to the claimed sequence that would result in a functional embodiment of the claimed invention.

Applicant has not responded to the rejection of Claim 23 for lacking guidance for using a method that both increases and decreases the fatty acid composition of a seed. Guidance is lacking for using the method of Claim 23 for both increasing and decreasing the fatty acid composition of a seed. The unpredictability in such an approach is inherently unpredictable considering the same starting materials are to be used in the same prescribed fashion to give opposite results.

Applicant has not responded to the enablement rejection with respect to the unpredictability in making amino acid substitutions at a particular site in a protein that completely eliminate activity as described in Kallis R. *et al.*, Plant Physiology, July 2000, Vol. 123; pp. 1077-1086. The reference shows 9 different changes the same position within a conserved phosphate binding loop of Rubisco activase resulted in mutant enzymes that showed both an increase and a decrease in their activity, but only one, the Q111V in Figure 1, column 2 on page 1078, showed elimination of any detectable activity and thus demonstrates the unpredictability of eliminating activity in any prescribed fashion.

Given the lack of guidance for making mutant delta-12 fatty acid desaturase constructs encoding non-functional enzymes, or for producing plants transformed with said polynucleotides that would result in either altered or reduced percent linoleic acid levels, decreased linolenic acid levels, and increased oleic acid levels in seeds of transformed plants, the breadth of the claims, and given the unpredictability in the art, undue trial and error experimentation would be needed by one skilled in the art to isolate a multitude of non-exemplified mutant delta-12 fatty acid

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desaturase polynucleotides, or to evaluate the ability of a multitude of non-exemplified mutant delta-12 fatty acid desaturase polynucleotides to alter the phenotype of a multitude of transformed plant species. Therefore, the invention is not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23 and 25 remain and new Claims 37-44 and 49-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are included in the rejection.

At Claim 23, "altered" is indefinite. It is not clear if "altered" refers to different level or different structure. Further, the claim is missing an expression step.

At Claim 23, and throughout the claims, recitation of "gene" is indefinite.

There is not a standard definition for this term, i.e., a gene can denote the coding region of an amino acid sequence or a gene can be defined as containing regulatory elements operably linked to the coding polynucleotide sequence encoding an amino acid sequence. If appropriate, the term "polynucleotide" can be used to denote nucleic acid molecules that encode a polypeptide. All subsequent recitations of "gene" are also rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

All claims remain rejected.

Claims 23, 25, 29 and 37-44 and 49-58 are deemed free of the prior art given the failure of the prior art to teach or reasonably suggest a transformed plant comprising a polynucleotide encoding a mutant microsomal delta 12 desaturase having a E to K change at amino acid position 106, wherein the levels of oleic acid are elevated and those of linoleic and linolenic are decreased.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
February 5, 2004


PHUONG T. BUI 2/9/04
PRIMARY EXAMINER